ATMOS
MedizinTechnik

English

Operating Instructions

ATMOS C 361

Surgical Suction Unit

CE 0124

340.0001.B
340.0002.B
340.0003.B
340.0004.B
340.0005.B
340.0351.B
340.0350.B

2013-09 Index: 15

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Contents

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1.1 Notes on operating instructions

- These operating instructions contain important notes on how to operate the **ATMOS C 361** safely, correctly and effectively. Therefore, they are intended not only for new operating personnel to be instructed in its use, but also for use as a reference manual. They help to avoid risks, and also to reduce repair costs and down-time. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions must always be kept available near the appliance.
  Prior to first use please peruse the chapter 2.0 “For your safety”, in order to be prepared for any possible dangerous situations. It would be too late during in actual use.

  The basic principles are:

  Judicious and careful work provides best protection against accidents!

  Operational safety and readiness for use depend not only on your capabilities, but also on care and maintenance given to the **ATMOS C 361**. For this reason regular cleaning and service work are a must. Major maintenance and repair work may be carried out only by expert personnel authorised by ATMOS. In case of repairs you should insist that original spare parts only are used. You will then have the warranty that operational safety, readiness for work and the value of your appliance will be preserved.

- The product **ATMOS C 361** bears CE marking CE-0124 according to the EEC guideline of the council for medical products 93/42/EEC and meets the basic requirements of annex I of this guideline.
  The declaration of conformity will be provided on request on indicating the serial number of the unit.

- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and ISO 13485.

- ATMOS will supply a service manual containing detailed circuit descriptions and schematics as well as information on adjustment and servicing to service organizations authorized by ATMOS.

- Reprints, also in extracts, only with written permission by ATMOS.

Abbreviations / symbols in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

☞ Indicating particularly important advice!

1.2 Intended use

The Surgical Suction Unit **ATMOS C 361** is a compact suction unit for medical application. It is especially intended for aspiration and collection of secretions, body fluids and tissue. Its main fields of application are:

– **in the OPD, in the OR:** for sucking off and collecting e.g. drain pockets, abscesses, body and rinsing solutions and during lipectomy;

– **in endoscopy:** e.g. to aspirate secretions or rinsing solutions as well as for operative fixation;

– **in gynaecology:** for suction curettage;

– **In ENT applications:** to aspirate secretions, rinsing solutions, cerumen or to extract foreign matters;

– **in the ward, recovery ward and ICU: :** for the spon-taneous aspiration of body fluids and foreign matters, e.g. from the respiratory tract.

The **ATMOS C 361** must **not** be used:

– in non-medical applications;
– to draw off combustible or explosive fluids or gases;
– for drainage in the low vacuum range (e.g. thorax drai nage);
– for smoke evacuation in connection with HF-electrosurgery or laser surgery.

1.3 Function

- The **ATMOS C 361** is a line-power operated surgical suction unit, centering around a silent diaphragm-type pump which generates a vacuum inside the secretion canister, allowing secretions to be withdrawn and collected. Using a vacuum regulator and the vacuum-gauge, the target vacuum and thus the air-flow rate can be precisely adjusted.

- Several secretion canisters of different sizes are available for use with the system (section 9.0 Spare parts and accessories). A hydrophobic bacterial filter in the lid of the secretion canister is implemented to prevent that secretions enter the pump resp. bacteria the interior of the unit.

- A trolley with standard rail is available for mobile use.

1.4 Explanation of symbols


Attention, refer to operating instructions !


Fuse


Potential equalization


Type BF equipment

~ Alternating current


Unit of protection class II

IPX1 Protection against penetration of damaging humidity (drop water)


Unit Off


Unit On

2.0 For your safety

- The design of the **ATMOS C 361** fulfills the requirements of IEC 601/EN 60601 and of protection class I. The device must only be connected to a properly installed socket with non-fused earthed wire.

- Before putting the device into operation, visually check unit, secretion canister, power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately. Check also function of the unit.

- The **ATMOS C 361** may be used in supervised operation by qualified personnel only which has been authorised by ATMOS and which has been trained for operating the appliance (IEC 601-1/EN 60601-1).

- The **ATMOS C 361** may be operated only in rooms used for medical purposes, but not in areas (zones M and G) subject to **explosion hazards and in oxygen rich environments**. Explosion harzards may result from the use of combustible anaesthetic agents, skin cleansing agents or disinfectants.

- Liquids must not be allowed to enter the device. Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.

- After transport at cold temperatures (below the freezing point), the unit must accli-matize prior to first use; leave it unoperated at room temperature for a period of up to 6 hours. If the unit is not acclimatized it must not be operated as the membranes of the pump might get damaged.

- Dispose of the packaging material, observing the applicable waste-control regulations.

- Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are similar to those indicated on the device.

- Never connect the unit to defective power sockets or extension cables.

- The suction hose must never come into direct contact with the application site. A suction catheter, attachment or a medical aspiration set must always be connected to the hose.

- When disconnecting the device from the power line, first remove the plug from the wall outlet. Then the power cord may be disconnected from the device. Never touch the plug or cord while your hands are wet.

- The ambient conditions specified in section 10.0 must be strictly observed.

- When using different canister systems there is a risk of contamination when operating the device without overflow protection/hydrophobic bacteria filter.
  Do not use the device respectively the canister without bacterial filter.

- There is a risk of an electric shock when liquid penetrated the overflow protection/hydrophobic bacteria filter.

- Set up the device so that the operator has a clear, unobstructed view of and easy access to the front panel. The device must be placed on a solid, level surface.

- The **ATMOS C 361** fully complies with the electromagnetic immunity requirements of standard **IEC 601-1-2 / EN 60601-1-2** "Electromagnetic compatibility - Medical Electrical Equipment".

- Warranty period for this unit: 2 years. This period is unaffected by any repair or maintenance carried out under the terms of the warranty. Please also pay attention to our enclosed General Standard Terms and Conditions.

- The warranty will be rendered invalid in case of damages caused due to the utilization of accessories or con-sumables which are not approved by ATMOS for use with this unit.

- ATMOS is not liable for personal injury and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorised by ATMOS.

- This operation manual corresponds with the construction of the unit and with the current status of safety-related standards at the time of printing. Proprietary rights are existing for all described circuits, processes, names, software programs and units.

- This product is not re-sterilisable. Repeated reuse of components which are marked with a ⊗ is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk

- Please do not store DDS filters under heavy objects since this may lead to deformation and with it to loss of function.
  There is a risk of contamination for the device.

Bild 1.

- Always set the equipment up on a secure, level surface.

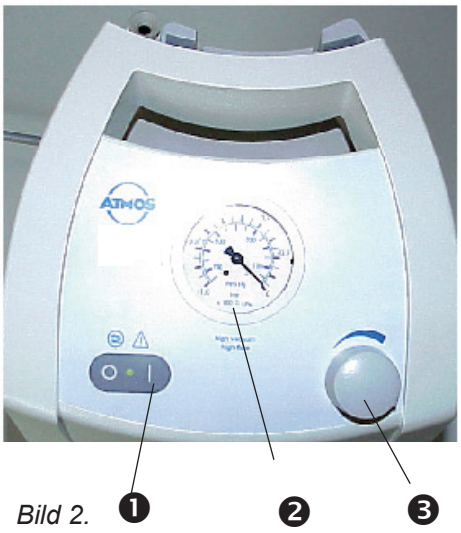

Bild 2.

3.1 Operating elements

❶ On/Off switch with pilot lamp
❷ Vaccuumgauge
❸ Vacuum controller

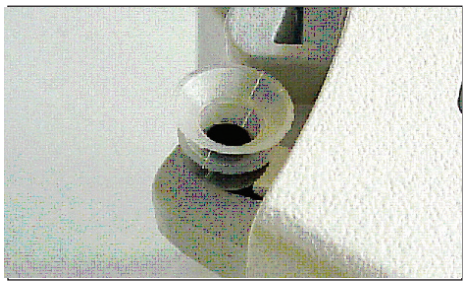

Bild 3.

Vacuum connection: Direct-Docking-System

☞ The vacuum connection between the pump and the secretion canister is created automatically as soon as the DDS canister is positioned correct-

Fig. 4.

3.2 Connection area in unit base

Connect mains cable

☞ Use only mains cables with angled inlet connector for non-heating appliances.

- Check that the voltage and frequency ratings of the power line are similar to those indicated on the device.

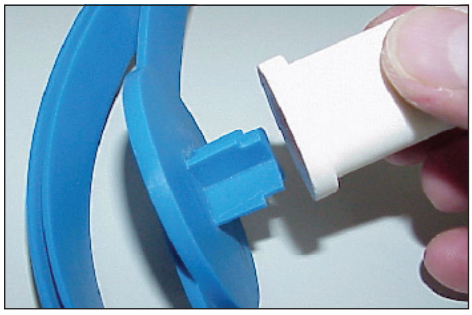

Fig. 5.

4.1 Insert / remove DDS bacterial filter /oversuction stop

☞ Use goves after having operated the unit!

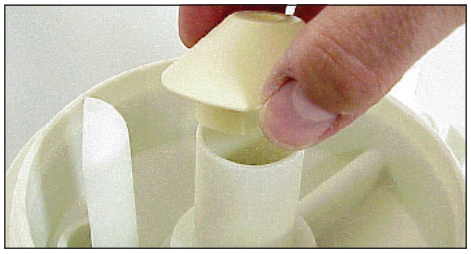

Fig. 6.

4.2 Using the DDS splash protector

Fig. 7.

4.3 Attach / remove DDS secretion canister lid

- With the DDS secretion canister on a firm surface, position the lid horizontally on top (the lid may not be twisted!)
- Press down lightly onto the secretion canister using both hands until limit is reached.

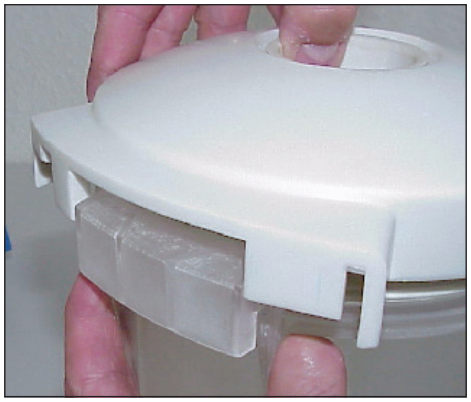

Fig. 8.

- To open the DDS secretion canister, hold the canister firmly by the reinforcing clips of the securing device and then pull the secretion canister lid up and off by gripping the filter

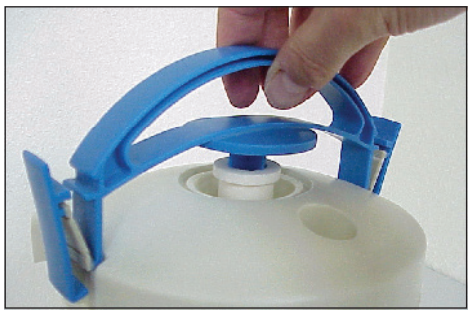

Fig. 9.

4.4 Attach DDS secretion canister handle

- Insert the DDS secretion canister handle into the grooves of the lid with the snap-in hooks open.

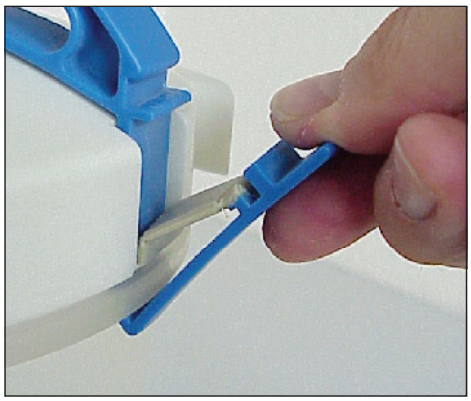

Fig. 10.

4.5 Close / open DDS secretion canister handle

- To close, secure the snap-in hooks under the edge of the secretion canister, and then press the clips downwards until they lock into place.
- To open, pull the clips upwards to release the snap-in hooks and remove from under the edge of the secretion canister.

Fig. 11.

4.6 Secure DDS secretion canister

- For removal, lift the DDS secretion canister vertically upwards; for insert it again, allow it to slide vertically downwards into the securing device.

Fig 11a.

4.7 DDS hose holder

- In the case that you would like to use the hose holder REF 340.0066.0 please mount it between the canister lid and the hose adapter as described in figure 11a.

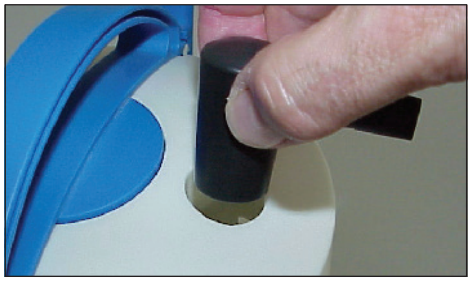

Fig. 12.

4.8 Insert DDS hose adapter

- Press the required DDS hose adapter with 6 or 10 mm diameter into the ”Patient” hole of the DDS secretion canister lid twisting slightly to ensure a tight fit.
- Twist slightly in the same manner when removing.

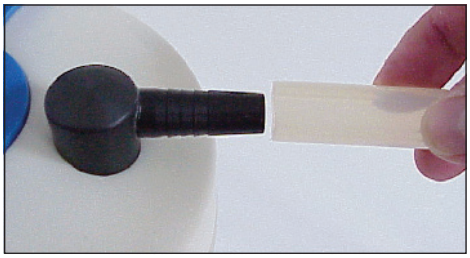

Fig. 13.

4.9 Connect hose

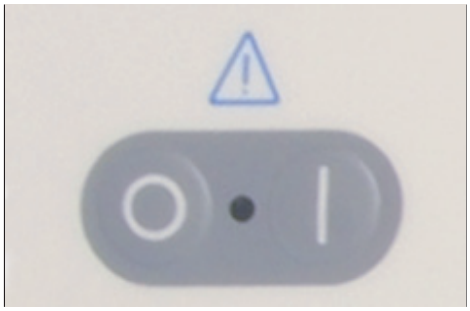

Fig. 14.

4.10 On / off switch

- Press the ”I” symbol to switch the unit on.
- Press the ”0” symbol to switch the unit off.

Fig. 15.

4.11 Set vacuum

- Close the suction hose and set the desired vacuum by turning the vacuum controller according to the direction of the arrow.

☞ Do not use force to turn the knob at its limits!

- Test the system for leaks if the desired vacuum is not achieved.

4.12 Suction

- Use appropriate suction catheters, suction tips or suction instruments.

☞ Prior to starting suction, containers must be checked for cracks. Damaged containers may not be used.

☞ Keep an eye on the level of liquid in the secretion canister during suction.

- The hydrophobic bacterial filter safely prevents liquid from getting into the pump. Nevertheless the secretion canister should be replaced when 2/3 full.

4.13 Test DDS bacterial filter / oversuction stop

- The DDS bacterial filter / oversuction stop is disposable.

☞ Before each use, check that the DDS bacteria filter / oversuction stop is clean and dry. Wet or dirty filters must be replaced with new ones. The filter is no longer in optimum condition if the vacuum displayed is above -0.3 bar when the vacuum controller is in the ”max.” position and the suction hose is open. The filter must then be replaced.

☞ Replace the DDS bacterial filter at least once a day. Use only original ATMOS bacterial filters!

☞ **Never operate the unit without the DDS bacterial filter / oversuction stop!**

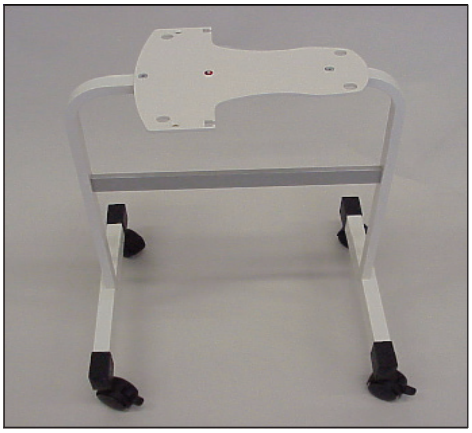

Fig. 16.

5.1 Trolley with standard rail

- A trolley with standard rail, which can also be used with disposable systems if necessary, is available for mobile use.
- Always position the trolley on a flat, sturdy surface.

5.1.1 Securing the unit

Fig. 17.

☞ It is only possible to ensure safe operation as a mobile suction unit by using the special trolley available for use with the unit!

- The suction unit is placed on the trolley so that it's feet lock into place in the holes of the unit carrier and it can be firmly attached to the unit carrier from underneath by means of a knurled screw.

☞ It is imperative that the unit is securely attached to the trolley to ensure safe operation and safe travel !

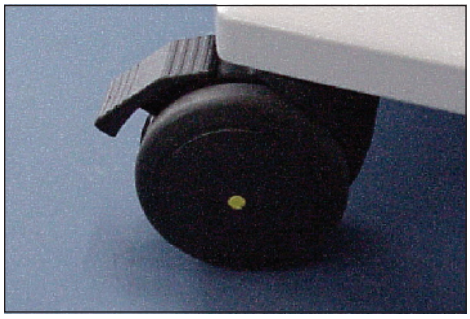

Fig. 18.

- Use the lockable castors if necessary.

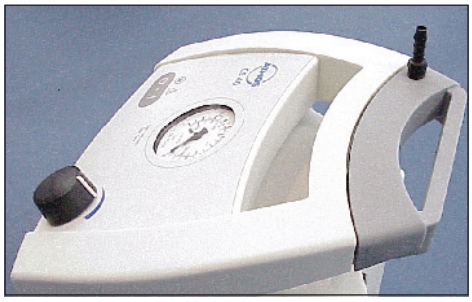

Fig. 19.

5.2 Use of suction unit with disposable systems

- The suction unit may be also used as a tabletop unit with disposable systems that can be attached to a standard rail.

- This requires the standard rail adapter with vacuum connector. Installation is performed in accordance with the attached installation instructions.

- Optionally the suction unit may also be used on the trolley with disposable systems that can be attached to a standard rail.

- When using the Receptal canisters the following supports have to be used:

2 x 1,5 l	REF 444.0027.0
1 x 2 l	REF 444.0030.0
2 x 2 l	REF 444.0028.0
1 x 3 l	REF 444.0031.0
2 x 3 l	REF 444.0029.0

6.1 General information on cleaning and disinfection

- For disinfection, you may use all surface and instrument disinfectants listed in chapters 6.4 / 6.5.

☞ A number of disinfection agents may cause discoloration at the secretion canister etc., however this has no effect upon the parts's function.

☞ Always observe the concentration specifications and instructions by the respective manufacturer !

6.2 Reprocessing of hoses and secretion canister

☞ Before using the device on a new patient be sure to clean and disinfect the following parts:

– DDS secretion canister including DDS secretion canister lid, DDS hose adapter and DDS secretion canister handle.
– Suction hose

- Unscrew all hose connectors, pull the DDS hose adapter out of the DDS secretion canister lid, open the lid, empty the secretion canister and dispose of the suctioned material properly.

- Take the DDS bacterial filter out of the DDS secretion canister handle.

- All other parts, except the bacterial filter, must also be thoroughly rinsed under running water. You may add a detergent, if you wish.
  Using the cleaning agent neodisher AN or neodisher MediClean forte (manufactured by Dr. Weigert, Hamburg) cleaning in an automatic cleaner and disinfecter is also possible.
  Thermal disinfection is carried out at 93° C.

- After disinfectation, reassemble all parts (section 4.0 "Operation").

- Autoclave all of the parts referred to above
  (134 °C, 3 bar, 5 min 3x fractionated prevacuum).

6.0 Cleaning

6.3 Cleaning and sterilizing the unit surface

☞ Always disconnect the device from the power line, before cleaning and disinfecting the surface.

- Wipe the surface clean with a cloth soaked in a cleaning solution or disinfectant. Liquids must not enter the device. All of the cleaning solutions and disinfectants listed below can be used.

☞ Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.

6.4 Recommended disinfectants for instruments

Disinfectant	*Contents*	*(in 100 g)*	*Manufacturer*
GIGASEPT FF neu (Anwendungskonzentrat)	succinic acid dialdehyde dimethoxy tetrahydrofurane corrosion inhibitors non-ionic tensides	11,0 g 3,0 g	Schülke & Mayr, Norderstedt
Sekusept aktiv	sodiumpercarbonate, phosphonates non-ionic tensides		Ecolab, Düsseldorf

6.5 Recommended disinfectants for surfaces

Disinfectant	**Contents**	**(in 100 g)**	**Manufacturer**
Mikrobac forte	benzyl - C12 - C18 - alkyldimeththyl - ammoniumchloride N- (3-Aminopropyl) - N - dodccylpropane- 1,3 - diamine	19,9 g 5,0 g	Bode Chemie, Hamburg
Green & Clean SK (Anwendungs-konzentrat)	alkyl-dimethyl-benzyl-ammoniumchloride dialkyl-dimethyl-ammoniumchloride	< 1 g	Metasys, Rum (Österreich)

6.6 Recommended cleaning agents

Disinfectant	**Ingredients**	**(in 100 g)**	**Manufacturer**
neodisher MediClean forte (Application concentrate)	non-ionic tensides NTA (nitrilotriacetic acid) enzymes, preservative agent	< 5 g 5-15 g	Dr. Weigert, Hamburg
neodisher AN	Phosphate non-ionic tensides enzymes	> 30 g < 5 g	Dr. Weigert, Hamburg

7.0 Maintenance

- Visually inspect the device, hoses, secretion canister and power cord before each use.
- For hygienic reasons, the bacterial filter must be replaced at least once a day !
- The unit does not require any further maintenance.

Maintenance

Before putting the device into operation, visually check unit, secretion canister and power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately!

However, every 2 years an inspection and a safety-related check according to EN/IEC 62353 have to be performed.

7.0 Maintenance

Repairs

The following may require repairs from the manufacturer or an authorized service partner. Prior to sending in the device, please contact your service partner by phone.

- Liquids have penetrated the device
- Sudden occurrence of unusual noises
- Operational and functional disorders which cannot be resolved by means of the hints describes in the chapter "Troubleshooting".

Measures to be taken prior to sending in the device:

If the device has to be sent in for repair after consultation with the manufacturer or an authorized service partner, we ask you to observe the following:

- Please send in the complete device (see scope of delivery).
- Please remove all disposable parts and consumables.
- Thorough cleaning and disinfection
- Airtight packing
- Please enclose a detailed error description.

Warranty

ATMOS cannot guarantee an error-free function nor can ATMOS be held liable for damage to people or goods if

- non-original ATMOS parts are used,
- the information in these operating instructions are disregarded,
- assembly, new installations, modifications, extensions and repairs are done by people who are not authorised by ATMOS.

7.1 Change fuse

- Remove mains cable.
- Press the spring clips of the fuse holder together on both sides with a small screwdriver and pull out the fuse holder.
- Replace the fuse and push the holder back in until both spring clips are locked into place.
- Then reconnect mains cable.

8.0 Trouble-shooting

The **ATMOS C 361** was subjected to a thorough quality control before shipment. If there is, nevertheless, some malfunction, you possibly might solve this problem yourselves if you observe the following instructions:

Problem	*Possible cauces*	*Remedy*
● Unit does not start	– Loose power plug	– Check connection to supply socket
	– no power voltage	– Check inbuilding fuse
	– Defective fuse	– Replace fuse
● Insufficient performance or no suction	– Leakages within the hose system or in the secretion canister lid	– Check secretion canister lid and hose system, replace sealing ring on secretion canister lid, if necessary
	– Filter is clogged (vacuumgauge indicates a vacuum)	– Replace filter, check filling level in secretion canister; evacuate canister,
if		necessary
	– Secretion or blood has been sucked in and valve plates of the pump are	– Unit has to be returned for repair

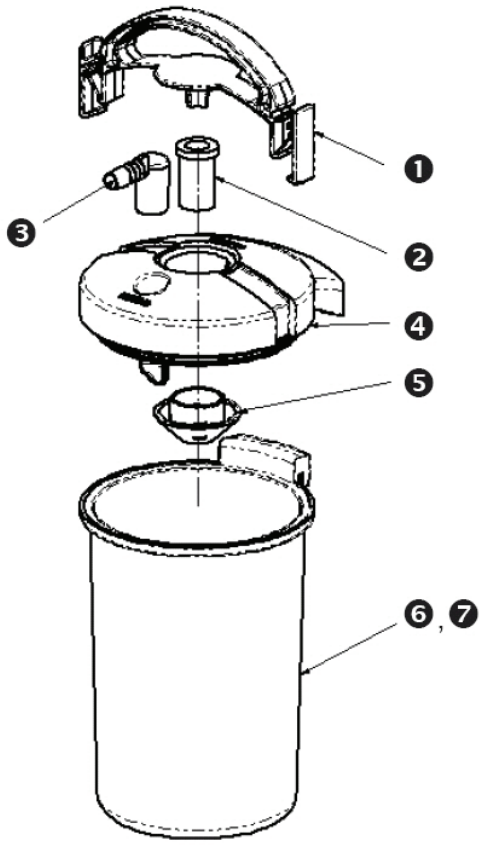

Fig. 20.

9.1 Spare parts

Description	*Article-No.*
❶ DDS-canister handle, PSU	340.0055.0
❷ DDS-bacterial filter / oversuction stop, hydrophobic, disposable part, price for 10 pcs.	340.0054.0
❸ DDS-hose adaptor set, Ø 6 + 10 mm	340.0057.0
❹ DDS-canister lid with gaskets	340.0053.0
❺ DDS-splash protection	340.0056.0
❻ DDS-secretion canister, polysulphone, 1.5 l	340.0050.0
❼ DDS-secretion canister, polysulphone, 3.0 l	340.0051.0
Expansion bellows, silicone rubber	000.0739.0
Fuse 230 V T 0.63 A/H	008.0634.0
Fuse 115 V T 1.25 A/H	008.0720.0
Mains cable angle-angle, 5 m	008.0818.0
Push-in foot for housing	505.0337.0
Clamping ring for fixing screw	000.0727.0
Operating instructions	340.0001.i

9.2 Accessories

9.2.1 Canisters

Description	Article-No.
DDS-secretion canister, polysulphone, 1.5 l	340.0050.0
DDS-secretion canister, polysulphone, 3 l	340.0051.0
DDS-canister lid with gaskets	340.0053.0
DDS-canister handle, PSU	340.0055.0
DDS-splash protection	340.0056.0
DDS-hose adaptor set, Ø 6 + 10 mm	340.0057.0

9.2.2 For ATMOS C 361 with trolley

Trolley with standard rail	320.0070.1
DDS-standard rail adaptor with vacuum connection for the use of disposable systems at the unit	340.0059.0
grad. secretion canister 3 l, glass	444.0033.0
grad. secretion canister 5 l, glass	444.0034.0
Secretion canister lid complete, for 3 l + 5 l glass canister	441.0208.1
Holder for 3 l glass canister	000.0040.0
Holder for 5 l glass canister	000.0041.0
Receptal container set II, support with 2 x collection container, Receptal®-canister 1,5 l	310.0221.0
Receptal® canister 2 l	444.0256.0
Receptal® canister 3 l	444.0157.0
Receptal® suction bag 1.5 l, not autoclavable, 50 pcs	310.0222.2
Receptal® disposable bag 2 l, without integrated overflow protection	443.0257.0
Receptal® suction bag 2 l, with integrated overflow protection	443.0257.2
Receptal® suction bag 3 l, without integrated overflow protection	444.0153.0
Receptal® suction bag 3 l, with integrated overflow protection	444.0154.0

9.2.3 Facilities to simplify the handling

Hose holder on canister	340.0066.0
Catheter quiver for flex. catheters, attached to trolley	444.0140.0
Catheter quiver with holder for rail system (for catheter storing)	443.0780.0
Quiver holder, small, incl. standard rail holder	444.0145.0
Hose holder, for attaching to standard rail (white plastic)	444.0450.0

10.0 Technical specifications

Air flow rate of pump	36 ± 4 l/min
Max. vacuum at sea level	-91kPa (-910 mbar or 682,5 mmHg)*@ NN
Vacuum readout	-1...0 bar ± 16 mbar(class 1.6)
Additional air regulation	mechanical regulating valve,ball vacuum regulator
Secretion canister	1.5 l or 3 l canisters made of polysulphone
Suction hose	ø 6 mm or ø 10 mm
Rated voltage	230 V~ 50/60 Hz, 340.0001.0
Rated current	approx. 0.45 A for 230 V~
Power consumption	approx. 100 W
Operating time	> 8 h of continuous operation without interruption, within 24 h
Fuses	T 630 mA/H for 230 V~
Protective earth conductor resistance	–
Earth leakage current	–
Enclosure leakage current	< 0,1 mA NC
Patient leakage current	–
Heat emission	max. 100 J/s
Noise level	< 50 dB (A) @ 1 m (ISO 7779)
Ambient conditions	
Transport/Storage	-30...+50°C 5...90 % humidity, non-condensing air pressure 700...1060 hPa
Operation	+5...+35°C 20...80 % humidity, non-condensing air pressure 700...1060 hPa
Dimensions	HxWxD H 330 x W 240 x D 360 mm (with secretion canister) H 900 x B 410 x T 450 mm(with trolley)
Weight	6.3 kg (with secretion canister)
Protection class (IEC 601)	II
Applied Part	Type BF
Degree of protection	IPX 1
Classification acc. to Annex IX EEC directing 93/42/EEC	IIa
CE marking	CE 0124
Rules applied	see annexed list
UMDNS-Code	10 - 217
Reference-No.	340.0001.0 230 V
Soundlevel:	< 50dB (A) @ 1 m (ISO 7779)
GMDN-Code:	36777
Canadian Classification	
Device Group	General & Plastic Surgery
PNC	79QBU
Risk Class	2
Description	ASPIRATOR, SURGICAL

*1 bar @ 750,06 mm Hg @ 1000 hPa / depends on daily atmospheric pressure

Rules applied:DIN EN 1041, DIN EN 1441, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN ISO 10079-1,DIN EN 980,DIN EN ISO 10993-1

Technical Specification 04.07.2011

10.0 Technical specifications

Canadian Classification
Device Group General & Plastic Surgery
PNC 79QBU
Risk Class 2
Description ASPIRATOR, SURGICAL

1 bar @ 750,06 mm Hg @ 1000 hPa / depends on daily atmospheric pressure

Rules applied:DIN EN 1041, DIN EN 1441, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN ISO 10079-1,DIN EN 980,DIN EN ISO 10993-1

Technical Specification 01.04.2005

11.1 Checking ATMOS suction devices

The ATMOS suction devices are maintenance-free in the case they are used according to the operating instructions. However, every 2 years an inspection and a safety-related check according to EN/IEC 62353 have to be performed.

Regular, thoroughly cleaning and disinfection of the hoses and the application parts respectively the operation in line with the operating instructions are assumed.

A regular check of the condensate-controller on the rear side is necessary. Pull out the plastic plug at check the colour at the end of the hose. In case of discolouration/deposits a maintenance measure must be performed by a certified ATMOS service partner!

11.2 Reprocessing

In case secretion was sucked into the device it may not be operated until it is repaired by the ATMOS service.

Handling of the suction device determines to a large extent its reliability and safety. The hygiene measures described in the previous chapters are necessary measures for the protection of patients and users, and to maintain functional reliability.

11.3 Disposal

- The ATMOS C 361 is not comprised of any hazardous materials.
- The materials of the housing can be recycled completely.
- Prior to disposal, device and accessories must be decontaminated.
- The materials are to be separated carefully.
- Pay attention to country-specific regulations for disposal (e. g. waste incineration).

Disposal within the EC

The suction device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professional. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) rules the disposal of electrical devices. Since this type of product is mainly used at home for secretion suction in the respiratory tract (after laryngectomy), it must be assumed that those suction devices could be contaminated. Therefore, this type of device is excluded from the law for electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Prior to disposal respectively before transport all secretion containers and hoses must be thoroughly cleaned and disinfected. The device surface must be disinfected.

12.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

12.1 Guidelines and Manufacturer´s Declaration - Emissions

The ATMOS C 401 and ATMOS C 361 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 401 and ATMOS C 361 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Harmonics IEC 61000-3-2	Class 1	The ATMOS C 401 und ATMOS C 361 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	match	

The device may not be used directly next to other devices or piled up with other devices.
If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

12.2 Guidelines and Manufaturer´s Declaration - Immunity

The ATMOS C 401 and ATMOS C 361 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 401 and ATMOS C 361 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air		Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os		Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 2 kV Common		Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS C 401 und ATMOS C 361 demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS C 401 und ATMOS C 361 from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

12.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS C 401 und ATMOS C 361 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 401 und ATMOS C 361 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the ATMOS C 401 und ATMOS C 361 incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** d = [3,5 / V_1] √**P** d = [3,5 / E_1] √**P** d = [7,0 / E_1] √**P** where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (*a*) survey, should be less than the compliance level (*b*). Interference may occur in the vicinity of equipment containing following symbol. 
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	

NOTE 1	With 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2	These guidelines don´t like to be applicable in any case. The propagation of electromangetic sizes is influenced by absorptions and reflections of buildings, objects and people.
a	The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS C 401 und ATMOS C 361 is used exceeds the above compliance level, the ATMOS C 401 und ATMOS C 361 is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.
b	Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

12.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 401 und ATMOS C 361

The ATMOS C 401 und ATMOS C 361 is intended for use in electromagnetic environment in which ratiated disturbances are controlled. The customer or user of the ATMOS C 401 und ATMOS C 361 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS C 401 und ATMOS C 361 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter **W**	**150 kHz to 80 MHz** **d =** [3,5 / V_1]$\sqrt{P}$	**80 MHz to 800 MHz** **d =** [3,5 / E_1] $\sqrt{P}$	**800 MHz to 2.5 GHz** **d =** [7,0 / E_1] $\sqrt{P}$
0.1			
0.1			
1			
10			
100			

For transmitters for which the maximum nominal output isn´t indicated in the above table, the recommended separation distance *d* in meters (m) can be determined using the equation belonging to the respective column whereas *P* is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer´s specification.

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines don´t like to be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE CE

Wir / We / Nous

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch/Germany
Tel. +49 7653 689-0

erklären in alleiniger Verantwortung, dass das Medizinprodukt /
declare under our sole responsibility that the medical device /
déclarons sous notre pleine et entière responsabilité que le produit médical

Klassifizierung / Classification / Classification : II a

Name / name / Nom: ATMOS C 361 ..... REF 340.0001.0

Varianten / models / Variante:

ATMOS C 361,
Praxispaket, 1,5 l 340.0002.0
ATMOS C 361,
Praxispaket, 3 l 340.0003.0
ATMOS C 361,
Praxispaket, mobil, 1,5 l .. 340.0351.0

ATMOS C 361,
Stations-Paket, 1,5 l..... 340.0004.0
ATMOS C 361,
Stations-Paket, 3 l 340.0005.0
ATMOS C 361,
Praxispaket, mobil, 3 l 340.0350.0

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht. /
meets all applicable requirements of the Directive 93/42/EEC /
répond à toutes les exigences applicables de la directive 93/42/CEE

Name, Adresse und Kennnummer der Benannten Stelle:
Name, address and identification number of Notified Body:
Nom, Adresse et Numéro d'identification de l'organisme notifié :

CE 0124

DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart

Konformitätsbewertungsverfahren:
Conformity assessment procedure:
Procédé d'évaluation de conformité :

Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007 / Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 / Directive 93/42/CEE, Annexe II du Conseil sur les produits médicaux, passée en commission le 14 juin 1993, dernière modification le 5 septembre 2007.

Gültig bis auf weitere Änderungen am Produkt bis 29. März 2015.
Valid till further changes on the product until March 29th 2015.
Valide jusqu'à modification du produit, jusqu'au 29 mars 2015.

Lenzkirch, den 04.06.2013
Place and date of issue

Frank Greiser
Geschäftsführer /
Managing Director / Directeur

i.V. Steffi Focke
Sicherheitsbeauftragter / Safety Inspector / Chargée de la Sécurité

ATMOS General terms and conditions

ATMOS MedizinTechnik

1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved.Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coin-cidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compen-sation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;

b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.

c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;

d. We accept no responsibility for damage defects caused by

- operational wear and tear;
- incorrect installation or incorrect or insufficient maintenance;
- incorrect operation of the product (in contradiction to the operating instructions delivered with the product); - improper use or operating faults; - inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation; - using accessories and/or replacement parts which are not explicitly approved;
- incorrect assembly and/or initial operation by the client or third parties; - the client's negligence in handling the product; - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.
- accidents, acts of God, especially lightening, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for tthat case. This also applies in the case of our culpable infringement of substantial contractual duties The indispensable conditions of German Liability Law remain unaffected thereby.
- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods repre-sents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income form such use is balanced against the client's arrears, after deducting appropriate utilisation costs.The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby.We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law.Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, September 2008
ATMOS MedizinTechnik GmbH & Co. KG
79853 Lenzkirch/Germany

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